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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,065	02/12/2002	Shyam S. Mohapatra	USF-T156X	2390
23557	7590	08/10/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/073,065	Applicant(s) MOHAPATRA ET AL.	
	Examiner Myron G. Hill	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 37-41, 45, 49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) 37-41, 45 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/18/05</u> . | 6) <input type="checkbox"/> Other: _____ |

HL

TD

DETAILED ACTION

The examiner of this application has changed, please address all future correspondence to Examiner M. Hill, AU 1648.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18, 2005 has been entered.

Claims 33 and 50 are under consideration.

Information Disclosure Statement

A signed and initialed copy of the IDS filed May 18, 2005 is enclosed with this action.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Necessitated By Amendment Based On Prior Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connors et al. in view of Li et al. (J Exp Med), Li et al. (Virology), and Leong et al. (all cited in the rejection of the canceled claim 35).

The claims are drawn to an immunogenic composition comprising nanospheres wherein said nanospheres comprise plasmid DNA coaservated with chitosan and the plasmids encode 9 RSV genes (M2, G, F, M, SH, NS1, NS2, N, and P.

Applicant argues that there is no reasonable expectation of success in the combined cited art, that an immune response to a composition comprising a combination of antigens cannot be predictably determined from the responses of the same antigens individually and cites art submitted in a concurrently filed IDS. Applicant cites interactions between the expressed proteins and that adding antigens to a multi-antigen cocktail reduces the dose of each antigen. Applicant argues that the art teaches that F and G are the main antigens to provide neutralizing antibodies.

Applicant argues that the instant disclosure shows that all nine antigens were expressed (citing Figures 1A, 1B, and 6A[sic] and page 14, lines 12-13).

Lastly, Applicant argues that the cited references do not teach how to make an immune response to 9 RSV antigens and that obvious to try is not the standard for 103(a) rejections.

Applicant's arguments have been fully considered and not found persuasive.

It is noted that the claims are drawn to an immunogenic composition comprising plasmids, a product. The claims do not require expression of all nine plasmids. One plasmid being expressed, for example RSV-F or RSV-G, is enough to make the product immunogenic. Furthermore, it is noted that the locations cited by applicant to show expression of 9 RSV antigens (Figures 1A, 1B, and 6A[sic] and page 14, lines 12-13) clearly show only expression of 7 genes (this is stated clearly in the text, page 14, line 12, and figure 6 does not show a lane for RSV-P and the band for SH, is not visible).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., expression of 9 antigens and immune response to 9 antigens) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, there are no limitations in the claims that require expression levels be a certain amount.

The arguments concerning dose and interaction of expressed proteins are not persuasive because the claims are drawn to a product that is immunogenic, not a

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method of inducing an immune response with a specific dose or combination of antigens.

Thus, knowing that chitosan coacervated plasmids of RSV can be used to raise an immune response and that multiple antigens can be used, claim 33 is unpatentable over the cited references.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connors et al., Li et al. (J Exp Med), Li et al. (Virology), and Leong et al. as applied to claim 33 above, and further in view of Illum (WO90/09780, previously cited) or Rolland et al. (USPat, previously cited) or Wyatt (Vaccine, from IDS, previously cited).

Claim 50 recites the same product as claim 33 but adds the limitation that the immunogenic composition is formulated as an inhalant.

Connors et al., Li et al. (J Exp Med), Li et al. (Virology), and Leong et al. have been discussed above and previously (Office Action of November 16, 2004).

Connors et al., Li et al. (J Exp Med), Li et al. (Virology), and Leong et al. do not teach inhalant formulation of the particles.

Illum or Rolland et al. or Wyatt et al. each teach that chitosan encapsulated DNA plasmid particles can be formulated as inhalants (Office Action of November 16, 2004, section 22).

One of ordinary skill in the art at the time of invention would have been motivated to formulate the particles as inhalants for inducing an immune response against RSV because RSV is a respiratory pathogen. One of ordinary skill in the art would have the

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expectation of success because RSV is known to be immunogenic and can be formulated as an inhalant.

No specific arguments have been provided for claim 45 as amended by Applicant but the general arguments by Applicant have been addressed above.

Thus, claim 45 is unpatentable over the cited references.

Conclusion

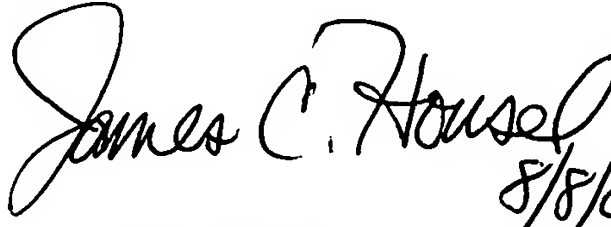
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MGH
8/5/05


JAMES HOUSEL
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8/8/05